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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 11 **CX/RVDF 21/25/12**

April 2021

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

25th Session
(Virtual)
12-16 and 20 July 2021

COMMENTS IN REPLY TO CL 2020/18-RVDF ON PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUTION BY THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

Comments received from Argentina, Brazil, Costa Rica, Cuba, Iran, Malaysia, Peru, Uganda and United States of America

Argentina

Argentina appreciates the opportunity to propose to this body the incorporation of active ingredients used in veterinary drugs to be included on the priority list for subsequent recommendation to JECFA for evaluation or re-evaluation and to provide the information according to the template in the Annex to this document.

Argentina wishes to *urge the Codex Alimentarius to establish MRLs for known active ingredients,* which remain an indispensable health tool for ranching practices in our region. Some of these *compounds* have been registered based on limits or tolerances that have since been discontinued by the agencies that established them or were evaluated many years ago with limited information that could be completed with current-day studies. The request for the competent bodies to provide an update and, subsequently, the lack of new data from the original sponsors have been cause for suspension or the MRL being outdated. *There is no scientific evidence that identifies concerns for human health that would merit suspending the use of these types of products. But the lack of benchmark limits has caused international trade issues.*

Based on the foregoing, Argentina would recommend JECFA evaluate *Ethion* and *Nicarbazin*, based on the attached forms.

RATIONALE:

There is no international MRL reference for Ethion. In the case of Nicarbazin, the 50th JECFA report, which evaluates this substance, observes that the MRL recommendation was based on the Limit of Quantification of the test method, thus the MRL recommendation of 200 ng/g for all poultry matrices (liver, fat, muscle, and kidney). Other countries have an even higher MRL (and thus less restrictive), such as the case of Australia, which has established an ADI equivalent to Codex, but with an MRL of 35000 ng/g for the poultry liver matrix.

It is imperative to have MRLs recommended by Codex Alimentarius that enable establishing appropriate, reliable withhold periods for current animal production practices, in order to ensure animal production food safety for animals treated with these products and avoid international trade issues.

The profile forms for each active ingredient are attached as annexes.

Part I. Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation

ANNEX I: NICARBAZIN

Part II. Veterinary drugs for which data availability should be confirmed at CCRVDF25

No additional information is available.

Part III. Veterinary drugs for which additional data / information is necessary to complete the JECFA evaluation

ANNEX II: ETHION

Part IV. Parallel review – Evaluation of a new compound

Argentina supports a parallel review of a new compound. No additional information is available.

ANNEX I

TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CCRVDF

ADMINISTRATIVE INFORMATION

1. Member submitting the request for inclusion: Argentina

2. Veterinary drug name: Ethion

3. Trade Names: Garrathion, Mosktion F; Mosktion PF; Mosktion AI

4. Chemical names and CAS registry number: Phosphorodithioic acid S,S'-methylene O,O,O',O'-tetraethyl ester.
CAS: 563-12-2

5. Names and addresses of basic producers: OVER SRL. Meghmani Organics Limited INDIA

PURPOSE, SCOPE AND RATIONALE

6. Identification of the food safety issue (residue hazard): Ethion residues in edible cattle tissue that could be cause for public health concern and/or issues with international trade of these products.

7. Assessment against the criteria for the inclusion on the priority list: This molecule has been used in veterinary products for decades. Products containing ethion are currently used in most of the countries of the region, primarily as a tickicide. At the time, it was registered based on the reference tolerance established by the EPA; but it is currently discontinued due to a lack of additional information from the sponsor when the EPA reviewed it, with no scientific evidence regarding health concerns. There is a new ADI established by JECFA in the report from its 85th meeting.
http://www.who.int/foodsafety/publications/jecfa-reports/en/

RISK PROFILE ELEMENTS

8. Justification for use: In Argentina, the emerging issue of resistance to *B. microplus* to conventional molecules and the minute possibility of new developments call for presenting alternative active ingredients that have been proven effective. Against this backdrop: Ethion is highly effective against ticks, and given the fact that ticks have not had contact with the proposed chemical in years, it is a valuable alternative as a tick-control tool for cattle (*Boophilus microplus*).

9. Veterinary use pattern, including information on approved uses if available (*this should include product labels or other evidence of official use authorization*): Labels for approved products are attached, in addition to the certificate of use and trade.

10. Commodities for which Codex MRLs are required: Cattle muscle, liver, kidney and fat.

RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS

11. Specific request to risk assessors: MRL recommendation for cattle muscle, liver, kidney and fat, based on the new ADI reference established by JECFA in the report from its 85th Meeting, available depletion studies (submitted at CL 2015/18-RVDF), and the unpublished radiolabeled ethion studies conducted in the USA.

AVAILABLE INFORMATION

When preparing a preliminary risk profile, Member(s) should take into account the updated data requirements, to enable evaluation of a veterinary drug for the establishment of an ADI and MRLs, published by JECFA.

12. Countries where the veterinary drug is registered:

- Argentina: Mosktion F 00-162; Mosktion PF Mosktion AI 03-172; Garrathion Max 15-104
- Colombia: Mosktion F Reg.I.C.A. No. 6826 MV.
- Ecuador: Mosktion PF 3B2-10556-AGROCALIDAD
- Nicaragua: Mosktion AI 9771
- Paraguay: Mosktion PF 7036; Mosktion AI 8706

13. National/Regional MRLs or any other applicable tolerances:

- MRLs (Argentina)
  - Muscle: 0.020 mg/kg
  - Kidney: 0.020 mg/kg
  - Liver: 0.020 mg/kg
  - Fat: 0.200 mg/kg

14. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available (*this should include a list of the data available with the full study titles*):

List of data submitted at CL 2015/18-RVDF:

- National Residue Survey Information Bulletin. Australian Government, Department of Agriculture, Fisheries and Forestry – November 2010. International beef maximum residue limits (MRLs)
- Ethion and cypermethrin residues in cattle treated with Garrathion max.
- Risk mitigation tests on ethion and cypermethrin in baths to remove the product once it has been used.
- Validation of analytical techniques to determine ethion and cypermethrin in edible tissue. http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Evaluation94/ethion.pdf

List of unpublished studies conducted with radiolabeled ethion:

- Bodden, R.M. and Zietlow, D.C. 1985. Poultry metabolism study on ethion. FMC Report No. PC 0026, by Hazelton Laboratories America, Inc., Madison, WI. Unpublished.
- Bosch, A. 1985. Metabolism study of 14C-labeled ethion in lactating goats. - Amendment No. 1, FMC Report No. PC-0033, by Hazelton Laboratories America, Inc., Madison, WI. Unpublished.
- Ellison, T. 1981a. Audit validation of the milk and tissue residue study on ethion in dairy cows. Report No. J8516. Unpublished.
- Ellison, T. 1981b. Audit validation of the study for the determination of ethion residues in chicken tissues and eggs. IBT Report No. J5425. Unpublished.
- Gohre, K. 1988. Metabolism of 14C-ethoxy labeled ethion in lactating goats. FMC Study No. 237GOAMO2. Unpublished.
- Gohre, K. 1991a. Metabolism of ethion in the goat - part I: Metabolite identification in urine, feces, milk and peritoneal fat. FMC Study No. 237GOAMO2-1. Unpublished.
- Gohre, K. 1991b. Metabolism of ethion in the goat - part II: metabolite identification in liver, kidney, heart and loin muscle. FMC Study No. 237GOAMO2-1. Unpublished.
- Shuttleworth, J.M. 1969. Determination of ethion residues in eggs and poultry tissues. FMC Report No. M-2548. Unpublished.
- Shuttleworth, J.M. 1971b. Residue determination of ethion and its oxygen analogs in milk and cow tissue. FMC Report No. M-2808. Unpublished.

Other available studies:

- Pharmacol Toxicol. 1991 Jul;69(1):34-7. Tissue distribution and urinary excretion of 14C-ethion in goats. Mosha RD(1). Author information: (1) Department of Pharmacology and Pathobiology, Royal Veterinary and Agricultural University, Frederiksberg C, Denmark.
- Bull Environ Contam Toxicol. 1990 Sep;45(3):375-81. Distribution and elimination of 14C-ethion in laying hens and eggs after oral exposure. Mosha RD (1), Gyrd-Hansen N, Nielsen P. Author information: (1) Department of Pharmacology and Toxicology, Royal Veterinary and Agricultural University, Denmark.
- Pharmacol Toxicol. 1990 Sep;67(3):246-51. Fate of ethion in goats after intravenous, oral and dermal administration. Mosha RD (1), Gyrd-Hansen N, Nielsen P. Author information: (1) Department of Pharmacology and Toxicology, Royal Veterinary and Agricultural University, Bülowsvej 13, Frederiksberg, Denmark.
- Vet Hum Toxicol. 1990 Feb;32(1):6-8. Toxicity of ethion in goats. Mosha RD (1), Gyrd-Hansen N. Author information: (1) Department of Pharmacology and Toxicology, Royal Veterinary and Agricultural University, Frederiksberg, Denmark.

TIMETABLE

15. Date when data could be submitted to JECFA: Studies with radiolabeled ethion were requested by the USA but were not obtained. In conjunction with Costa Rica and Uruguay, a cooperation project was devised with financing from the IAEA to conduct the study on radiolabeling; but due to the extraordinary circumstances of 2020 in relation to the SARS-CoV-2 pandemic, the project and necessary studies did not occur. The project is expected to come to fruition in 2021.

ANNEX II

TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CCRVDF

1. Member submitting the request for inclusion: ARGENTINA

2. Veterinary drug name: Nicarbazin

3. Trade Name: Nicarbazin

4. Chemical names and CAS registry number: N,N'-bis-(4-NITROPHENYL)UREA AND 4,6-DIMETHYL-2(1H)-PYRIMIDINONE (equimolar complex); 4,4'-DINITROCARBANILIDE AND 4,6-DIMETHYL-2-PYRIMIDINOL (equimolar complex).
CAS registry number: 330-95-0

5. Name and address of basic producers: Elanco Animal Health, Inc. 2500 Innovation Way, Greenfield, IN 46140 USA (contact: Jesse Sevcik, jsevcik@elanco.com)

PURPOSE, SCOPE AND RATIONALE

6. Identification of the food safety issue (residue hazard): Re-evaluation of nicarbazin MRLs in poultry muscle, fat / skin, liver, and kidney, due to recent changes in overall withhold periods for nicarbazin use. With the implementation of withhold periods from day zero in EMA, USA, Canada, Malaysia, Australia, and New Zealand, there is greater risk that poultry tissues exceed the Codex MRL when used according to the approved product label and good veterinary practices. The current Codex food basket for nicarbazin consumes just a fraction of the accepted daily intake for nicarbazin; as such, current MRLs for nicarbazin can be adjusted to alleviate trade restrictions, without posing safety risks to the consumer. Current Codex standards to not reflect current treatment modalities for this veterinary drug, nor do they reflect the new residue data generated to support withhold periods from day zero approved in many parts of the world.

7. Assessment against the criteria for the inclusion on the priority list: Argentina proposed the compound be re-evaluated.

- Good veterinary practices with an updated treatment modality are authorized in several Codex member countries.
- The enforcement of existing Codex standards has given rise to trade issues.
- The compound is widely available in many member countries.
- A sponsor has committed to providing the necessary data for evaluation.

RISK PROFILE ELEMENTS

8. Justification for use: The veterinary drug is commonly registered in combination with narasin (in equal parts) as an anticoccidial drug “to prevent coccidiosis in broiler chickens caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E . maxima. "

9. Veterinary use pattern, including information on approved uses if available (*this should include product labels or other evidence of official use authorization*):

- Australia (Label / MRLs)
- Canada (Medicating ingredient brochure/MRLs)
- European Union (Scientific Opinion / Authorization # 51 772)
- New Zealand (Label/MRLs)
- United States of America (NADA 138-952 / Label)

10. Commodities for which Codex MRLs are required: Chicken muscle, liver, kidney and fat.

RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS

11. Specific request to risk assessors: Member countries evaluated the data from the studies and changed the treatment modality on the use of nicarbazin, when used in an equal combination of narasin, from 5 to 7 days to zero days of withhold.

AVAILABLE INFORMATION

12. Countries where the veterinary drug is registered: Algeria, Argentina, Australia, Bangladesh, Barbados, Belarus, Bolivia, Bosnia and Herzegovina, Brazil, Cambodia, Canada, Chile, People’s Republic of China, Colombia, Costa Rica, Croatia, Dominican Republic, Ecuador, Egypt, El Salvador, European Union, Guatemala, Honduras, Hong Kong, India, Indonesia, Iran (Islamic Republic), Iraq, Israel, Jamaica, Jordan, Kazakhstan, Kenya, Republic of Korea, Lebanon, Libya, Malaysia, Mexico, Morocco, Namibia, New Zealand, Nicaragua, Oman, Pakistan, Panama, Paraguay, Peru, Philippines, Russian Federation, Saudi Arabia, Serbia, South Africa, Sri Lanka, Switzerland, Syrian Arab Republic, Taiwan (Province of China), Thailand, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Arab Emirates, USA, Uruguay, Venezuela, and Vietnam.

13. National/Regional MRLs or any other applicable tolerances:

Country	Liver	Kidney	Muscle	Skin / Fat	Giblets
Tolerances / MRLs (µg/kg)					
European Union	15000	6000	4000	4000	--
USA	52000	--	--	--	--
Canada	15000	8000	4000	4000	--
Australia	35000	20000	5000	10000	
Malaysia	4000	4000	4000	4000	
New Zealand			4000	4000	15000

14. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available (*this should include a list of the data available with the full study titles*):

New data and studies:

- Johnston, Deborah L. (2008) Residue Depletion of Nicarbazin and Narasin in Edible Tissues from Chickens Following Administration of Maxiban® G160 via Feed. T4HAUK0703
- Lloyd (2009a). Pilot Laboratory Study: Relative Bioavailability of DNC In Rats Administered Alone, Mixed With HDP and as Nicarbazin. Study 130-136.
- Coleman, Mark R., Rodewald, John M., Brunelle, Sharon L., Nelson, Maria, Bailey, Lauryn, Burnett, Thomas J., Determination and Confirmation of Nicarbazin, Measured as 4,4-Dinitrocarbanilide (DNC), in Chicken Tissues by Liquid Chromatography with Tandem Mass Spectrometry, Journal of AOAC International, 97, 2, 2014.
- Harrison, Laura, Mizinga, Kemmy, Determination of Narasin and Nicarbazin Stability in Chicken Tissues, Covance Laboratories, Greenfield, IN, 2017. ELA1600366
- Harrison, Laura, Mizinga, Kemmy, Determination of Nicarbazin Stability in Chicken Liver Tissue Extract, Covance Laboratories, Greenfield, IN, 2017. ELA1700465.
- Rodewald, John M., Supplemental Validation of a Method for the Determination and Confirmation of Nicarbazin in Chicken Tissues by LC-MS/MS, Covance, Greenfield, IN, 2014. 8290-857.
- Edwards, Tracye, Supplemental Dilution Linearity Validation of Nicarbazin in Poultry Liver and Kidney to Support AOAC First Action Method 2013.07, Eurofins, Greenfield, IN, 2019. ELA1900171.
- Brunelle, Sharon L., LaBudde, Robert A., Lombardi, Kimberly, Ward, Clive, Determination and Identification of Nicarbazin, Measured as 4,4'-Dinitrocarbanilide (DNC), in Chicken Tissues by Liquid Chromatography with Tandem Mass Spectrometry: Final Action Official Method 2013.07., Journal of AOAC International, In Review, 2020.

TIMETABLE

15. Date when data could be submitted to JECFA: The data will be available for submission in March 2021.

Brazil

Brazil would like to inform that unfortunately we have no proposals for veterinary drugs to be included to the priority list for subsequent recommendation to JECFA for evaluation or reevaluation.

Costa Rica

Costa Rica would like to thank the JECFA and the CCRVDF for the great work done and the opportunity to comment. In this regard, CR would like to make the following comments:

1. Part I. Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation

Costa Rica supports the Priority List of Veterinary Drugs for Evaluation or Re-evaluation, because this list allows a better prioritization of veterinary medicine evaluation. However, for the time being, Costa Rica does not propose the inclusion of other medicines to that list, because it considers best to first allow to complete the evaluation of the drugs already on the list before adding new drugs to it. Otherwise, we could end up with an overblown list, which would defeat the initial purpose of this list by having too many drugs without their evaluation (which is the current situation of substances not on the list).

2. Part II. Veterinary drugs for which data availability should be confirmed at CCRVDF25.

Costa Rica supports maintaining ethoxyquin for evaluation as a feed additive, though we do not have data to add to that evaluation.

3. Part III. Veterinary drugs for which additional data / information is necessary to complete the JECFA evaluation

Costa Rica supports that, if possible, the evaluation of ethion, flumethrin and sisapronil be completed, though regrettably we do not have data to support that evaluation.

4. Part IV. Parallel review – Evaluation of a new compound

Costa Rica supports the parallel evaluation modality for veterinary drugs and supports the continuing evaluation of selamectin, though we have no data to add to the evaluation of that veterinary drug.

Cuba

We have nothing to contribute in regard to this circular letter.

Malaysia

TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CCRVDF

ADMINISTRATIVE INFORMATION

1. Member(s) submitting the request for inclusion: Malaysia
2. Veterinary drug names: Nicarbazin
3. Trade names: Nicarbazin
4. Chemical names:

   N,N'-bis-(4-NITROPHENYL)UREA AND 4,6-DIMETHYL-2(1H)-PYRIMIDINONE (equimolar complex); 4,4'-DINITROCARBANILIDE AND 4,6-DIMETHYL-2-PYRIMIDINOL (equimolar complex)

   CAS registry number: 330-95-0
5. Names and addresses of basic producers: Elanco Animal Health, Inc. 2500 Innovation Way, Greenfield, IN 46140 USA (contact: Jesse Sevcik, jsevcik@elanco.com)

PURPOSE, SCOPE AND RATIONALE

6. Identification of the food safety issue (residue hazard):

   A re-evaluation of nicarbazin MRLs of muscle, fat/skin, liver, and kidney of chicken due to recent changes to global withdrawal times for nicarbazin use in poultry. With the implementation of a zero-day withdrawal times in EMA, US, Canada, Malaysia, Australia and New Zealand, there is an increased risk for poultry tissues to exceed the Codex MRL when used according to the approved product label and good veterinary practice. The current Codex nicarbazin food basket consumes only a fraction of the nicarbazin ADI; as such, adjustments to the current nicarbazin MRLs, to alleviate trade restrictions, can be made without a risk to consumer safety. The current Codex standards do not reflect current treatment modalities for this veterinary medicine, nor the new residue data generated to support zero-day withdrawal times approved around the world..
7. Assessment against the criteria for the inclusion on the priority list:
   a. Malaysia is proposing the compound for evaluation.
   b. Good veterinary practices with the updated treatment modality is authorized in several Codex Member Countries.
   c. The application of existing Codex standards has led to trade problems.
   d. The compound is widely available in many Member Countries.
   e. A sponsor has committed to providing data necessary for the evaluation.

RISK PROFILE ELEMENTS

8. Justification for use:

   The veterinary medicine is commonly registered in combination with narasin (in equal parts) as an anticoccidial “for the prevention of coccidiosis in broiler chickens caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima.”

9. Veterinary use pattern, including information on approved uses if available (this should include product labels or other evidence of official use authorization):

   Australia (Label / MRLs)
   Canada (Medicating ingredient brochure/MRLs)
   European Union (Scientific Opinion / Authorization # 51 772)
   New Zealand (Label/MRLs)
   United States (NADA 138-952 / Label)

10. Commodities for which Codex MRLs are required: Chicken

RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS

11. Specific request to risk assessors: Member Countries evaluated data from studies and changed the treatment modality for the use of nicarbazin, when used in equal combination of narasin, from 5 or 7 days to zero days of withdrawal.

AVAILABLE INFORMATION

12. Countries where the veterinary drugs are registered: Algeria, Argentina, Australia, Bangladesh, Barbados, Belarus, Bolivia, Bosnia and Herzegovina, Brazil, Cambodia, Canada, Chile, the People's Republic of China, Colombia, Costa Rica, Croatia, Dominican Republic, Ecuador, Egypt, El Salvador, European Union, Guatemala, Honduras, Hong Kong, India, Indonesia, Iran (Islamic Republic of), Iraq, Israel, Jamaica, Jordan, Kazakhstan, Kenya, Republic of Korea, Lebanon, Libya, Malaysia, Mexico, Morocco, Namibia, New Zealand, Nicaragua, Oman, Pakistan, Panama, Paraguay, Peru, Philippines, Russian Federation, Saudi Arabia, Serbia, South Africa, Sri Lanka, Switzerland, Syrian Arab Republic, Taiwan (Province of China), Thailand, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Arab Emirates, United States of America, Uruguay, Venezuela, and Viet Nam.

13. National/Regional MRLs or any other applicable tolerances:

Country	**Liver**	**Kidney**	**Muscle**	**Skin/Fat**	**Offal**
Tolerance/MRL (µg/kg)					
European Union	15000	6000	4000	4000	--
United States	52000	--	--	--	--
Canada	15000	8000	4000	4000	--
Australia	35000	20000	5000	10000	
Malaysia	4000	4000	4000		
New Zealand			4000	4000	15000

14. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available (this should include a list of the data available with the full study titles and whether the compound is also registered as pesticide and, as appropriate, has been evaluated or scheduled for evaluation or re-evaluation by JMPR)

    Data to be Submitted:

    - Johnston, Deborah L. (2008) Residue Depletion of Nicarbazin and Narasin in Edible Tissues from Chickens Following Administration of Maxiban® G160 via Feed. T4HAUK0703.
    - Lloyd (2009a). Pilot Laboratory Study: Relative Bioavailability of DNC In Rats
    - Administered Alone, Mixed With HDP and as Nicarbazin. Study 130-136.
    - Coleman, Mark R., Rodewald, John M., Brunelle, Sharon L., Nelson, Maria, Bailey Lauryn, Burnett, Thomas J., Determination and Confirmation of Nicarbazin, Measured as 4,4-Dinitrocarbanilide (DNC), in Chicken Tissues by Liquid Chromatography with Tandem Mass Spectrometry, Journal of AOAC International, 97, 2, 2014.
    - Harrison, Laura, Mizinga, Kemmy, Determination of NArasina nd Nicarbazin Stability in Chicken Tissues, Covance Laboratories, Greenfield, IN, 2017. ELA1600366.
    - Harrison, Laura, Mizinga, Kemmy, Determination of Nicarbazin Stability in Chicken Liver Tissue Extract, Covance Laboratories, Greenfield, IN, 2017. ELA1700465.
    - Rodewald, John M., Supplemental Validation of a Method for the Determination and

- Confirmation of Nicarbazin in Chicken Tissues by LC-MS/MS, Covance, Greenfield, IN, 2014. 8290-857.
- Edwards, Tracye, Supplemental Dilution Linearity Validation of Nicarbazin in Poultry Liver and Kidney to Support AOAC First Action Method 2013.07, Eurofins , Greenfield, IN, 2019. ELA1900171.
- Brunelle, Sharon L., LaBudde, Robert A., Lombardi, Kimberly, Ward, Clive, Determination and Identification of Nicarbazin, Measured as 4,4'-Dinitrocarbanilide (DNC), in Chicken Tissues by Liquid Chromatography with Tandem Mass Spectrometry: Final Action Official Method 2013.07., Journal of AOAC International, In Review, 2020.

TIMETABLE

15. Date when data could be submitted to JECFA. March 2021.

Peru

Part I. Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation

In accordance with numeral 4 in the Circular Letter, we propose considering the need for MRLs for Norfloxacin. To this end, attached is the "Template for Information Necessary for Prioritization by CCRVDF."

Part II. Veterinary drugs for which data availability should be confirmed at CCRVDF25

Regarding ethoxyquin (used as feed additive), the CCRVDF does not have relevant data or information to support evaluation of this compound. However, it is reported that, through Implementing Regulation (EU) 2017/962, the European Union has suspended authorization of ethoxachine as a feed additive for all animal species and classes. Therefore, these indications have been taken into account for products to be exported to that trade group.

Part III. Veterinary drugs for which additional data / information is necessary to complete the JECFA evaluation

Regarding the compounds ethion, flumethrin, fosfomycin and sisapronil, no data or information is available to support completing the evaluation of these compounds.

It is worth noting that SENASA has 51 veterinary products registered with the drug fosfomycin, of which 13 are imported from Colombia, Argentina, and Mexico.

The National Fish Health Service (SANIPES) has a product of Mexican origin registered with fosfomycin, which is authorized by the competent health authority.

It should be noted that The Japan Food Chemical Research Foundation has established an MRL of 0.5 ppm for muscle, fat, liver, kidney and edible offals, and 0.05 for milk and fish. Furthermore, the Food Safety Commission of Japan presented a risk assessment report on fosfomycin, which determined an ADI of 0.019 mg/kg of live weight per day. This information was submitted by Argentina at the Codex session CRD - CL 2016/41-RVDF8.

Part IV. Parallel review: Evaluation of a new compound

Regarding selamectin, no data or information is available to support evaluation of this compound.

In Peru, there are no selamectin-based products registered for food-producing species**.** The products registered with SENASA are for use in pets (dogs and cats).

It bears noting that this active ingredient is being developed for controlling sea lice infestations in Atlantic salmon species. In Peru, the farmed species of salmonids is rainbow trout (Oncorhynchus mykiss), which is known to be vulnerable to sea lice. This external parasite is present in marine environments and affects trout in farming systems using farming cages in the open sea, which is a system that is not currently used in this country. As this is a target species that is not found in our national territory, we do not have information to contribute on this matter.

TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CCRVDF

ADMINISTRATIVE INFORMATION

1. Member submitting the request for inclusion: Peru
2. Veterinary drug name: Norfloxacin

3. Trade names:

No.	**SENASA REGISTRATION**	**TRADE NAME**	**TARGET SPECIES**
1	F0304N150	AMOXINOR	Poultry and swine
2	F0310N0668	AMOXINOR - F	Poultry and swine
3	F0304N0667	AMOXINOR - S	Poultry
4	F8270N0397	AVNOR	Poultry and swine
5	F8270N0066	AXINOR PLUS	Poultry and swine
6	F8270N0468	BIO AVIPLEX FARM AMOXICILINA 30% + NORFLOXACINO HCL 20%	Poultry and swine
7	F8270N0438	BIO AVIPLEX FARM SULFATRINOR	Poultry and swine
8	F0375N1890	DERMASSAN	Cattle, canines, equines, felines
9	F5026N0017	DIARREVETXTRA	Cattle, South American camelidae, goats, sheep, equines
10	F8232I0267	FARMAFLOX	Poultry
11	F8270I0619	NOR - 70	Poultry and swine
12	F8270N0559	NORAMOX	Poultry and swine
13	F0370N1533	NORAMOX SOLUBLE	Poultry and swine
14	F8270N0627	NORAMOX-COR	Poultry and swine
15	F0370N1865	NORAMOX-KERN	Poultry and swine
16	F8226N0123	NORAX S PLUS	Poultry and swine
17	F0304N176	NORCARE	Poultry and swine
18	F0332N1275	NORFIN 20	Poultry and swine
19	F0320N1400	NORFLAMOX	Poultry and swine
20	F0370N1744	NORFLAMOX RP	Poultry and swine
21	F0370N1857	NORFLOR 25	Poultry and swine
22	F8270I0041	NORFLOX POLVO SOLUBLE	Poultry
23	F8232I0089	NORFLOXACIN LH 20%	Poultry
24	F0332N1440	NORFLYN 20%	Poultry and swine
25	F8232N0108	NORFLYN 25%	Poultry and swine
26	F0326N1273	NOR-MAX	Poultry and swine
27	F0326N1466	NOROXIN	Poultry
28	F8232N0303	NORVET	Poultry and swine
29	F0304N089	NORVET 20	Poultry and swine
30	F0370N1528	NOVAMOX	Poultry and swine
31	F0320N1430	NOVAMOX PREMIX	Poultry and swine
32	F0326N0854	PULMOBIOT PS	Poultry and swine
33	F8226N0146	QUINOBROX	Poultry and swine
34	F8226N0178	RESPILAB	Poultry and swine
35	F0370N1786	RESPIREND NFC	Poultry
36	F0326N1024	RESPIREND-S	Poultry and swine
37	F8270I0105	SANEFLOX POLVO SOLUBLE	Poultry and swine
38	F0326N1467	SNT INNOVA	Poultry
39	F0370N1525	SULFANOR	Poultry
40	F8270N0138	SULFATRIN	Poultry and swine

4. Chemical names and CAS registry number:
Chemical name:
1-ethyl-6-fluoro-4-oxo-7-(piperazin-1-yl)-1,4-dihydro-quinoline-3-carboxylic acid.
CAS number: 70458-96-7

Country	**Manufacturer**	**Address**
Brazil	FARMABASE SAUDE ANIMAL LTDA.	Praça Emilio Marconato, 1000, Galpao A3-Jaguariúna (SP)
Brazil	FORMIL VETERINARIA LTDA.	Estrada Velha de Itú, 800 - Vila Márcia Jandira - SP- Cep: 06612-250
Brazil	INTERCHANGE VETERINÁRIA INDÚSTRIA E COMÉRCIO LTDA.	R. Angelo Esteves, 51 Jardim Myriam Campinas-SP
Colombia	ALURA ANIMAL HEALTH & NUTRITION S.A.S.	Carrera 129 N° 22B-57 Interior 23
El Salvador	LIVISTO, S.A. DE C.V.	Carretera al Puerto de La Libertad Km 20 Zaragoza, La Libertad
Peru	AGROVET S.A.	Av. Javier Prado este N° 2935 Urb. San Borja-Lima
Peru	ANDES COMMERCE CORPORATION S.A.C.	Jiron Luis Garibaldi N° 1230 Urb. San German, La Victoria-Lima
Peru	BIO AVIPLEX S.A.C.	Calle Icaza Contreras Alfredo N° 148 Dpto 1 Int. 2 Urb. San Roque-Lima
Peru	CKM S.A.C.	Calle Horacio Cachay Diaz N° 328 -330 Urb. Sta Catalina, La Victoria-Lima
Peru	CORPORACION DE INVERSIONES Y SERVICIOS S.A.C.	Calle San Hector N° 275 Urb. Santa Luisa- Lima
Peru	CORPORATION AV PRODUCTS S.A.C.	Jr. Monterrey N° 341 Int. 404 Urb. Chacarilla del estanque-Lima
Peru	ILENDER PERU S.A.	Calle dos N° 199 Urb. Corpac- San Isidro-Lima
Peru	LABORATORIO QUIMICO VETERINARIO LABET S.A.C. - LABET S.A.C.	Mz. A Lote 2 Urb. Sol de Santa María, Carabayllo-Lima
Peru	LABORATORIOS BIOMONT S.A.	Av. Industrial 184 Ur. Aurora, Ate-Lima
Peru	LABORATORIOS DE PRODUCTOS VETERINARIOS S.A.C.	Calle Los Cerezos 106 Urb. Recaudadores, Ate-Lima
Peru	LABORATORIOS DROGAVET S.A.C.	Av. Los Condores Mz A Lote K1c Urb. El Club, Lurigancho-Chosica-Lima
Peru	LOS SAUCES REPRESENTACIONES S.A.C.	Calle 4 Mz T Lote 2 Urb. Nuevo Lurin, Lurin-Lima
Peru	MONTANA S.A.	Av. Los Rosales 290 Zona Industrial Santa Anita-Lima
Peru	PHARMA VET CORPORATION S.A.C.	Autopista Ramiro Priale 4833 Urb. Santa Maria de Huachipa, Lurigancho Chosica-Lima
Peru	PHARTEC S.A.C.	Calle Doña Ana 393 Urb. Los Rosales, Santiago de Surco-Lima
Peru	QUIMTIA S.A.	Las Praderas de Lurin MZ A y B, Lotes 1 y 2, Lurin-Lima
Peru	PHARMADIX CORP S.A.C.	Av. Santa Lucia 218 Urb. Ind La Aurora, Ate-Lima
Peru	LABORATORIOS MARETHFARM S.A.	Calle Los Algarrobos Mz J-1 Lote 16 Cooperativa Umamarca, San Juan de Miraflores-Lima

5. Names and addresses of basic producers:

PURPOSE, SCOPE AND RATIONALE

6. Identification of the food safety issue (residue hazard): Quinolones are a group of synthetic antimicrobial agents used in humans and veterinary medicine. These compounds are active against a wide range of gram-negative and gram-positive bacteria. The presence of quinolone residue in animal-derived food poses a health risk as it may be toxic and lead to hypersensitivity reactions and arthropathies.

7. Assessment against the criteria for the inclusion on the priority list:

- A member has proposed the compound for evaluation (a template for information recommended for consideration in the priority list by Codex Committee on Residues of Veterinary Drugs in Foods has been completed and is available to the Committee). The requested information has been completed in the respective template.
- The compound has the potential to cause public health and/or international trade problems: Yes, according to the WHO List of Critically Important Antimicrobials for Human Medicine, quinolones are classified as critically important antimicrobials and are further classified as "Highest Priority."
- The compound is available as a commercial product: Yes, it is available. In item 3, the products are described with their trade names as registered in Peru.

RISK PROFILE ELEMENTS

8. Justification for use: Norfloxacin is a fluoroquinolone or second-generation quinolone. The wide range of applications and types of diseases it treats make fluoroquinolones extremely important for veterinary medicine.

   Fluoroquinolones are critically important for treatment of septicemias as well as respiratory and digestive infections. They are used in poultry, swine, cattle, goats, sheep and rabbits *(Source: OIE, List of Antimicrobial Agents of Veterinary Importance)*

9. Veterinary use pattern, including information on approved uses, if available (this should include product labels or other evidence of official use authorization)

   See: https://servicios.senasa.gob.pe/SIGIAWeb/ip_productofarmaco.html to find the veterinary products registered with the Official Authority (SENASA) that contain the drug Norfloxacin or Norfloxacin associated with other antimicrobials. Additionally, attached are examples of information and labels from some registered products.

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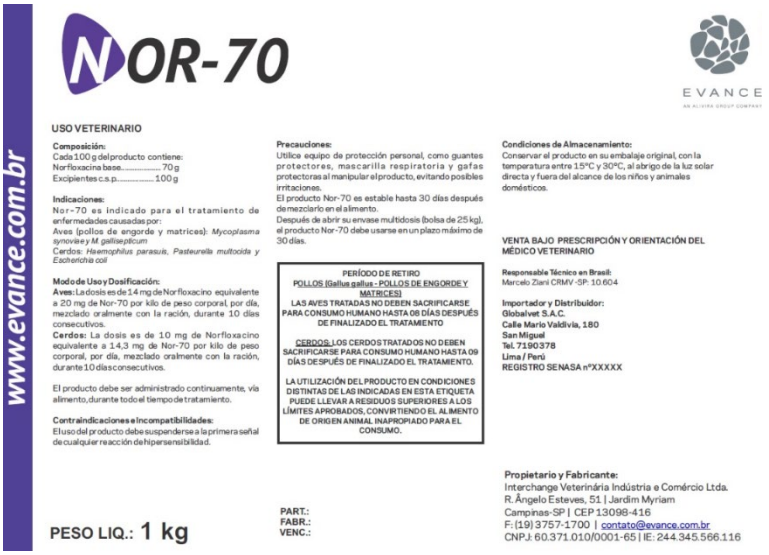
Instructions for Use	Label
AMOXINOR: Norfloxacin + amoxicillin trihydrate Poultry: For treatment of chronic respiratory disease, colibacillosis, mycoplasmosis, salmonellosis, coryza, colitis and necrotic enteritis due to *Clostridium sp*. Swine: For treatment of enzootic pneumonia and atrophic rhinitis, infectious digestive processes caused by enterobacteria such as *Salmonella*, colitis and enteritis with liquid and bloody feces caused by *Clostridium.*	

AVNOR: Norfloxacin + amoxicillin Poultry and swine: Indicated for the control of respiratory diseases, digestive processes caused by enterobacteria (E. *coli, Salmonella*, etc.) and also genitourinary infections caused by gram-negative microorganisms (enterobacteria and pseudomonas) and gram-positive bacteria (*Staphylococcus and Streptococcus*).	**AVNOR** **USO VETERINARIO** **Contenido Neto: 15 kg.** **FORMULA** Cada kg. Contiene: Amoxicilina Trihidrato..... 150 g Norfloxacina Nicotinato ..... 100 g Excipientes c.s.p.....1000 g **INDICACIONES** **AVNOR** es un producto que está indicado para el control de enfermedades respiratorias, procesos digestivos causados por enterobacterias (*E. Coli Salmonella*, etc) y también de infecciones genito urinarias causadas por microorganismos gram negativos (enterobacterias y pseudomonas), bacterias gram positivas (*Staphylococcus y Streptococcus*). **ESPECIES DE DESTINO:** Aves y Porcinos **DOSIS** AVES Y PORCINOS 1 a 2 kg por Tonelada de alimento de 5 a 7 días. **VIA DE ADMINISTRACION:** En el alimento concentrado. **TIEMPO DE RETIRO** No administrar durante 15 días antes del sacrificio de los animales destinados al consumo humano. **Mantener fuera del alcance de los niños.** **Debe conservarse en lugares secos y ventilados a temperaturas entre 15 a 30°C** **ELABORADO POR:** **PREMEZCLAS LATINOAMERICANAS S.A.** **R.U.C. 20522445445** Av. Los Eucaliptos Nro. 371 Int. 2-6 Sector Santa Genoveva (Esquina Calle Los Ceibos Parcelas 3-4) Lima - Lima – Lurin. **ELABORADO PARA:** **CORPORATION AV PRODUCTS S.A.C.** **RUC: 20603954263** **Jr. Antúnez de Mayolo #891 – Surco** **Teléfono: 408-2467 - Email: administracion@avproducts.pe** **M.V. Williams Olivos Salazar C.M.V.P. 3290** **Lote:** **REGISTRO DE SENASA Nº:** **Fecha de Fabricación:** **PRODUCTO PERUANO** **Fecha de Expiración:**
BIO AVIPLEX FARM SULFATRINOR: Norfloxacin + sulfamethoxazole + trimethoprim Swine: Post-weaning diarrhea caused by E.coli, gastrointestinal infections due to salmonellosis, meningitis and pneumonia, atrophic rhinitis. Secondary bacterial infections caused by *Pasteurella multocida, Actinobacilus pleuropneumoniae*, *Streptococcus spp and Haemophilus parasuis*. Poultry: Colibacillosis, coccidiosis, pasteurellosis, infectious coryza caused by Avibacterium paragallinarum	**BIO AVIPLEX FARM SULFATRINOR** **INDICACIONES:** EBIO AVIPLEX FARM SULFATRINOR producto indicado en el agua de bebida o en el alimento para el control y tratamiento de: Cerdos: Diarrea post-destete causada por: *E.coli*, infecciones gastrointestinales por salmonelosis, meningitis y neumonía, rinitis atrófica. Infecciones bacterianas secundarias provocadas por *Pasteurella multocida, Actinobacillus pleuropneumoniae, Streptococcus spp. y Haemophilus parasuis*. Aves de carne: Colibacilosis, coccidiosis, pasteurelosis, coriza infecciosa provocada por *Avibacterium paragallinarum*. **Agentes etiológicos susceptibles:** *Pasteurella multocida, Actinobacillus pleuropneumoniae, Streptococcus spp. y Haemophilus parasuis, Bacillus, Brucella, Cryptosporidium, Listeria, Erysipelothrix, Chlamydia, Toxoplasma, coccidios, Salmonella, E. coli, Mycoplasma, Rickettsiae, Avibacterium paragallinarum* Especies de destino: Aves y cerdos. FORMULA: Cada 100 g contiene: Sulfametoxazol ..... 20 g Trimetoprim ..... 4 g Norfloxacino ..... 16 g Excipientes c.s.p. ..... 100 g **Vía de administración:** Oral, mezclado con el alimento o disuelto en el agua de bebida. **Dosificación:** Aves y cerdos: 125 mg / Kg de peso vivo. **Intervalo y Duración del tratamiento:** Cada 24 horas por un período de 3 - 7 días. **Periodo de retiro:** Aves y cerdos: carne: 12 días. **Precauciones:** Preparar la mezcla diariamente, asegurándose de eliminar los restos del día anterior. En general no mezclar con antibióticos del tipo bacteriostático ya que limitarían a la acción de la Norfloxacina. Mezclar adecuadamente el producto en el alimento o disolver en el agua de bebida. **Contraindicaciones:** No usar en caso de hipersensibilidad a la sustancia activa y/o alguno de los excipientes. No usar en animales con insuficiencia renal y/o hepática. No se debe administrar en gallinas de postura, porque el huevo puede adquirir concentraciones del antibiótico. Ocasionalmente produce eritema, petequias, hemorragias internas y hematuria. **Condiciones de almacenamiento:** El producto se almacenará dentro de un rango de temperatura de 15- 30 °C, en lugar seco y protegido del sol. Mantener alejado del alcance de los niños. Elaborado por: Laboratorios Marathfarm SA Para: BIO AVIPLEX SAC RUC: 20601075548 Icaza Contreras Alfredo Nro. 148 Dpto. 1 Int. 2 Número de registro oficial: 00003021 Responsable técnico: Ciro Espilo Campusano C.M.V.P. 2360 REG. SENASA: Lote N°: F. Fab.: F. Venc.: **1 Kg** Contenido Neto USO VETERINARIO- VENTA BAJO RECETA
DIARREVETXTRA: Norfloxacin + colloidal kaolin + tannic acid + sulfadimethoxine + bismuth subnitrate Colibacillosis or white diarrhea, haemorrhagic enteritis, enterotoxemia, red diarrhea, bacillary diarrhea, salmonellosis, coccidiosis and nonspecific diarrhea. For cattle, equines, sheep, goats and South American camelidae.	**DIARREVETXTRA** **CON ELECTROLITOS** **TRATAMIENTO INTEGRAL DE LAS DIARREAS** **CONTENIDO: 25 g** **COMPOSICION** **CADA 100 g CONTIENEN** Principios activos: Norfloxacina 4,50 g Caolín coloidal 25,00 g Ácido tánico 10,00 g Sulfadimetoxina 6,20 g Subnitrato de bismuto 15,00 g Excipientes: Glucosa 15,30 g Cloruro de sodio 11,87 g Bicarbonato de sodio 10,44 g Cloruro de potasio 1,69 g • PARA USO VETERINARIO LABORATORIOS DE PRODUCTOS VETERINARIOS S.A.C. PRODUCTO PERUANO **PROPIEDADES:** Poderoso compuesto para el tratamiento integral de las diarreas de etiología diversa. Su potente acción se debe a la magnífica combinación de sus componentes en los que se incluyen los electrolitos indispensables para superar el proceso de deshidratación de los animales afectados y la sfucosa como fuente de energía de fácil utilización. **INDICACIONES:** Colibacilosis o Diarrea blanca, Enteritis hemorrágica, Enterotoxemia, Diarrea roja, Diarrea bacilar, Disentería, Salmonelosis, coccidiosis y diarreas inespecíficas. **ADMINISTRACIÓN Y DOSIS:** DIARREVETXTRA se administra por vía oral disuelto en abundante agua o leche por espacio de 3 a 5 días en las siguientes dosis: VACUNOS Y EQUINOS: 40 g por cada 45 kg de peso vivo. Continuar con 20 g por cada 45 kg de peso vivo cada 24 horas (una vez al día). OVINOS, CAPRINOS Y CAMÉLIDOS SUDAMERICANOS: 14 g por cada 15 kg de peso vivo. Continuar con 7 g por cada 15 kg de peso vivo cada 24 horas (una vez al día). **CONTRAINDICACIONES:** No administrar a animales con disfunción renal o hepática. No administrar conjuntamente con cloranfenicol o rifampicina. No administrar a ponedoras en producción de huevos para consumo humano. No administrar a vacas en producción de leche para consumo humano. **PRECAUCIÓN:** No exceder los 5 días de tratamiento. Administrar abundante agua de bebida a los animales en tratamiento. **PERIODO DE RETIRO:** Carne: 7 días. Conservar en lugar fresco y seco a menos de 25 °C, protegido de la luz. MANTÉNGASE FUERA DEL ALCANCE DE LOS NIÑOS. Venta Libre. Se recomienda el asesoramiento por parte del profesional veterinario. Elaborado por: Laboratorios Retapsa S.A. Cal. Salermo y Gamarra N°180, Urb. El Bosque, Rímac - Lima Distribuido por: Laboratorios de Productos Veterinarios S.A.C. Los Cerezos 106 Urb. Recaudadores de Salamanca, Ate - Lima / Tel. 341-0069 Correo: provetsac@gmail.com Prof. Resp.: Dr. Raúl Héctor Rosadio Alcántara LOTE N°: R.I. N° 02030-D FECHA FAB.: Reg. SENASA N°: FECHA VENC.:

FARMAFLOX: Norfloxacin Indicated for poultry in the treatment of respiratory and enteric diseases caused by *Escherichia coli, Salmonella enteritidis, Salmonella typhimurium and Salmonella gallinarum.*	
NOR-70: Norfloxacin Indicated for treatment of diseases in: Poultry: *Mycoplasma synoviae and M. gallisepticum* Swine: *Haemophilus parasuis, Pasteurella multocida and Escherichia coli.*	
NORFLOX SOLUBLE POWDER: Norfloxacin Poultry: For treatment of diseases caused by *Haemophylus sp, Staphylococcus, Escherichia coli, Mycoplasma sp, Pasteurella sp, Streptococcus sp.*	

10. Commodities for which Codex MRLs are required: Out of the 40 registered products containing norfloxacin, 30 products are intended for poultry and swine; 8 for poultry, 1 product for cattle, camelidae, goats, equines and sheep; and 1 product for cattle, canines, equines and felines.

The majority of products are intended for poultry and swine; thus, the following matrices would be prioritized:

Poultry	Muscle Liver Kidney Fat
Swine	Muscle Liver Kidney Fat

RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS

11. Specific request to risk assessors: Given that it is a critically important antimicrobial, and from a public health standpoint, it is important to understand the persistence of norfloxacin in foods (muscle, liver, kidney, fat) derived from animals that have received therapeutic treatment. Understanding the ADIs and MRLs would help to establish drug withholding periods for the animals that receive treatment.

AVAILABLE INFORMATION

12. Countries where the veterinary drug is registered: Brazil, Colombia, El Salvador, Peru

13. National/Regional MRLs or any other applicable tolerances: There are no national MRLS; neither are they found in Codex Alimentarius, the European Union or in the United States either. However, there are MRLs established by The Japan Food Chemical Research Foundation.

Table of MRLs for Agricultural Chemicals Change search method

< Item name Search at "n"

Agricultural Chemical : **NORFLOXACIN**

Note :

Excel Download

Display items

Food Type	MRLs(ppm)	Basis of setting	Note	MRLs(ppm) (Time limit for application)
Pig, muscle	0.02	Ab2016		
Pig, fat	0.02	Ab2016		
Pig, liver	0.02	Ab2016		
Pig, kidney	0.02	Ab2016		
Pig, edible offal	0.02	Ab2016		
Chicken, muscle	0.02	Ab2016		
Chicken, fat	0.02	Ab2016		
Chicken, liver	0.02	Ab2016		
Chicken, kidney	0.02	Ab2016		
Chicken, edible offal	0.02	Ab2016		

14. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available (*this should include a list of the data available with the full study titles and whether the compound is also registered as pesticide and, as appropriate, has been evaluated or scheduled for evaluation or re-evaluation by JMPR*)

    It acts at the intracellular level and inhibits the "A" subunits of DNA gyrase, an essential enzyme for coiling and supercoiling of bacterial DNA, an action that prevents its duplication and makes it prone to breakage. Norfloxacin is absorbed rapidly but incompletely after oral administration. Its bioavailability is close to 70%. Foods and antacids delay absorption. It has discrete binding to plasmatic proteins (15%) and is widely distributed in the body, reaching high concentrations in various fluids and tissues, especially in the kidney, urine, bile and feces. It partially metabolizes in the liver, where some active metabolites are produced. It is excreted in the urine by glomerular filtration and tubular secretion. It is also eliminated in significant quantities through bile and feces.

    https://www.who.int/foodsafety/publications/cia2017es.pdf
    http://db.ffcr.or.jp/front/pesticide_detail?id=50000

TIMETABLE

15. Date when data could be submitted to JECFA: The information described in this template is available to be sent whenever deemed appropriate.

Uganda

Uganda is in agreement with the priority list come up by JECFA.

Justification: Uganda currently does not have country data to submit thus is in agreement with JECFA.

United States of America

The United States would like to provide comments on the Circular Letter requesting information on the Priority List of Veterinary Drugs for Evaluation or Re-Evaluation by JECFA (CL 2020/18-RVDF).

Part III. Veterinary drugs for which additional data/information is necessary to complete the JECFA evaluation

The United States proposes to hold sisapronil on the Priority List for Re-Evaluation in "Part B – Compounds for which data availability will be confirmed at the next CCRVDF." The United States is not yet able to confirm the availability of additional information to continue the JECFA evaluation. We would request the Committee's consideration for additional time to respond to the information needs identified by the previous JECFA evaluation.

Part IV. Parallel review – Evaluation of a new compound

The United States would like to thank JECFA for their willingness to conduct a pilot evaluation of a compound while it was still under review by a national authority for registration. The United States would support continuation of the pilot evaluation and can confirm availability of additional information required to complete the evaluation by JECFA.

The United States would also like to support the proposed Parallel Review approach for JECFA evaluation in general. The Parallel Review approach could potentially shorten the time between a national approval and the establishment of Codex MRLs, which would support the mission of Codex to protect the health of consumers and ensure fair practices in the food trade.